

REMARKS

Claims 9, 10, 12, 13, 16, 17, 24 - 29 are pending. Claims 6, 7, and 8 are cancelled. Claims 9, 10, 12, 13, 16, and 17 have been amended to depend either directly or indirectly from claim 28.

Claim 29 is amended to correct its dependency. This amendment is believed to render moot the outstanding rejection under 35 USC 112, second paragraph.

No new matter is added by this amendment.

I. *Claims 12, 13 and claim 28 are rejected under 35 USC 102(b) as being anticipated by Horwitz, US Patent No. 5,108,745 (the '745 patent).*

Applicants respectfully traverse this rejection.

While the claims of Horwitz provide for (in part) “at least one extracellular product” of *Mycobacterium tuberculosis*, the organism name “*Mycobacterium tuberculosis*” does not even appear in the specification. Since the specification does not contain the term “mycobacterium” or “mycobacteria”, there can be no teaching of any subunit thereof. There is no teaching of the use of a polymeric carrier for any *Mycobacterium* polypeptide.

Thus, Horwitz does not teach the present invention.

Despite these facts, the examiner has requested evidence that the “extracellular products” of Horwitz do not read on the polypeptides recited in the claimed invention, which polypeptides are upregulated or expressed during the latent stage of mycobacteria infection. *It is noted that the examiner has never raised a rejection under 35 USC 103 against these claims and it is requested that the finality of the last action be withdrawn if this was in fact the examiner's intention.*

Applicants are submitting this evidence as requested by the examiner in a Declaration pursuant to Rule 132. Accompanying this Declaration are the declarations used by Horwitz to show that his “extracellular products” were in fact secreted antigens. Also supplied are later publications by Horwitz describing his secreted antigen. Thus, although Horwitz itself is not enabling for the subject matter recited in its tuberculosis vaccine claims, the supporting evidence he supplied and his later publications provide

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evidence that his "extracellular products" are not polypeptides upregulated or expressed during the latent stage of mycobacteria infection which are recited in the claimed invention.

Further, even these supporting documents do not teach or suggest the use of the types of carriers or vaccines of the present invention, all elements of which must be taken into consideration.

For all of these reasons, Horwitz does not teach or suggest the present invention.

Reconsideration and withdrawal of the rejection is requested.

II. Claims 6-10, 12, 13, 16, 17 and 24-27 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

Applicant respectfully traverses this rejection.

Claims 28 and 29 are free of this rejection. The remaining claims have been cancelled, rendering the rejection moot, or depend from independent claim 29.

Reconsideration and withdrawal of this rejection is requested.

Please charge any deficiency in any fee to deposit account number 08-3040.

Respectfully Submitted,
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